

"There is little judicial precedent to guide the court in the matter of the decision required here. Without doubt the release of the product to the claimant for the purpose of bringing same into compliance with the Act is a matter of judicial discretion. Here was a perfectly good food product, without harm in itself or to its users, condemned essentially because of the advertising and promotional material used in connection with its sale. The discretion of the court was exercised in the light of the purpose of the Act together with the principle that forfeitures are not favored.

"While the decision of the administrative body deserves respect, the decision in *Buticaps Inc. v. U.S.*, 252 F. 2d 634 indicates that the ultimate judgment of the sufficiency of relabeling is the obligation of the court.

But the terms and conditions are to be fixed by the Court and not by the Department of Health, Education & Welfare. Libelee is entitled to judicial due process. (*Buticaps v. U.S.*, supra, page 636.)

"Turning now to the merits, this court finds that the item involved is a food product. It is a mixture of honey and vinegar. Its components are plainly stated upon the proposed labels. The claimant has never been involved in previous similar law violations. Its good faith is not questioned. The libelant's contention that the article cannot be successfully sold as a food is an economic problem, the burden of which rests upon the claimant rather than upon the United States or the court. A similar product is presently marketed by at least two companies. That a segment of the public is impressed that a food product has certain therapeutic values is common to many food items in everyday use. The marketing of such items is within the law so long as baseless claims are eliminated therefrom.

"All of the above leads to the finding and conclusion that the steps proposed to be taken by the claimant in its letter of June 29, 1960, together with the amendment which strikes the words 'Fareham Farms' from the label and substitutes the words 'Sweet 'n Sour' brings the product into compliance with the law and the claimant is entitled to a judgment or order accordingly.

"The authorities cited by the United States have not been overlooked but in general they apply to the exercise of discretion in the release of a condemned product to the claimant for the purpose of bringing same into compliance with the law rather than to the question which is involved here. An order or judgment may be submitted accordingly."

In accordance with the above decision, the court entered an order on 12-22-60 directing that the article be relabeled to designate the trade name of the article as "Sweet'n Sour Honey and Vinegar," and that the original labels and all advertising and promotional material accompanying the article be destroyed.

**6485. Geriatric Formula Food Supplement.** (F.D.C. No. 44726. S. No. 23-236 R.)

**QUANTITY:** 14 cases each containing 24 186-tablet boxes, at Omaha, Nebr.

**SHIPPED:** 2-29-60 and 3-14-60, from Los Angeles, Calif., by Belco Products Corp.

**LABEL IN PART:** (Box) "XDR Geriatric Formula Food Supplement Plus \* \* \*  
A special formula from 100% Organic or Natural Sources with the exclusive XDR Base."

**ACCOMPANYING LABELING:** Leaflet entitled "Here is the story of XDR."

**LIBELED:** 7-20-60, Dist. Nebr.

**CHARGE:** 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for and preventive of physical and mental tiredness and depressed conditions; lack of vigor; rundown conditions; weakened blood; lack of resistance in conditions affecting capillary integrity and intercellular cement substances; colds; lack of health and proper sex function; prolonged illness

from any cause; loss of appetite; nervousness; neuritis; loss of muscle tone; digestive upsets; diarrhea; vague aches and pains; irritability; headache; constipation; reddening of the lips; dizziness; dryness of hair or skin; insomnia; indigestion; loss of weight; weakness; swelling and redness of the tongue or inflammation of the tongue or mouth; sores about the angle of the mouth; dental caries; anemia; defective teeth and gums; sponginess of gums; pyorrhea; gum infections; local hemorrhages of the nose, mouth, gums, and about the face; pale complexion; retarded development; lowered vitality; decreased red blood cells and hemoglobin; and night blindness; 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment for and prevention of cancer, impure blood, heart disease, ulcers, and for reducing, which were the purposes for which the article was offered in oral statements made during a sales presentation on 6-1-60, by the dealer, Andy S. Hansen, at Omaha, Nebr.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12-6-60. Consent—destruction.

**6486. Fresca powder.** (F.D.C. No. 44577. S. No. 36-440 R.)

QUANTITY: 67 8-oz. jars at Philadelphia, Pa.

SHIPPED: 2-29-60, from Dinuba, Calif., by The House of Fresca.

LABEL IN PART: "Fresca Powder \* \* \* a Medicinal Powder for Feminine Hygiene containing boric acid, alum, oil of peppermint and carbolic acid, especially prepared for use as a Douche."

LIBELED: 5-17-60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the jar label contained the false and misleading representations that the article was an adequate and effective treatment for vaginal irritations, cuts, skin abrasions, insect bites, prickly heat, chafing, "other irritations of the skin," and offensive, tender, and sore feet; and also the false and misleading statements "for use as a Douche for beneficial satisfying results" and "This powder is a high quality prescription and has fittingly proven its merits," which indicated that the article was offered for disease conditions for which it was not efficacious; and 502(f) (2)—when shipped, the labeling failed to bear the required warning statement for douche preparations, namely, "Warning: Do not use more often than twice weekly unless directed by a physician."

DISPOSITION: 12-7-60. Default—destruction.

#### DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

**6487. Various drugs.** (Inj. No. 376.)

COMPLAINT FOR INJUNCTION FILED: 3-21-60, N. Dist. N.Y., against Rand Pharmaceutical Co., Inc., Rensselaer, N.Y.

CHARGE: The complaint alleged that the defendant was in the business of preparing, selling, and introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, drugs which were adulterated and misbranded as follows: 501(b)—the articles purported to be drugs, the names of which were recognized in an official compendium, namely, the United States Pharmacopeia, and their strength